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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:

10/511,050

Filed:

October 12, 2004

1st Inventor:

M. Kusaka

For:

Preventives/Remedies for Hot Flash

Atty. Dkt. No.

3040 US0P

Art Unit:

1615

Examiner:

tba

Allowed

Batch

Paper No.:

Information Disclosure Statement

Commissioner for Patents P.O. Box 1450 Alexandria, VA 23313-1450

Sir:

Pursuant to 37 CFR §1.56, 1.97 and 1.98, Applicants' request consideration of the reference listed on the attached form PTO-1449 under §1.97(b). Copies of the foreign patent documents and non-patent literature documents are enclosed.

This statement is being timely filed before the mailing of a first Office Action on the merits. No fee is required for this filing.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call Applicants' attorney.

Respectfully submitted,

Dated: July <u>21</u>, 2005

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Claim M Rumesh

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Attorney for Applicants Customer No. 23115

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U.S. Patent Application Serial No.: 10/511,050



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of 2

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Complete if Known				
Application Number	10/511,050			
Filing Date	October 12, 2004			
First Named Inventor	M. Kusaka			
Art Unit	1615			
Examiner Name	tba			
Attorney Docket Number	3040 US0P			

			U. S. PATENT	DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		^{US-} 5,817,819	10-06-1998	Takeda Chemical Industries, Ltd.	
		^{US-} 6,187,788	02-13-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,514,988	02-04-2003	Takeda Chemical Industries, Ltd.	
		^{US-} 6,048,863	04-11-2000	Takeda Chemical Industries, Ltd.	
		^{US-} 6,180,792	01-30-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,297,379	10-02-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,340,686	01-22-2002	Takeda Chemical Industries, Ltd.	
		^{US-} 5,744,479	04-28-1998	Takeda Chemical Industries, Ltd.	
		^{US-} 6,001,850	12-14-1999	Takeda Chemical Industries, Ltd.	
		^{US-} 6,262,267	07-17-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,297,255	10-02-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,329,388	12-11-2001	Takeda Chemical Industries, Ltd.	
		^{US-} 6,194,419	02-27-2001	Takeda Chemical Industries, Ltd.	
	<u> </u>	^{US-} 6,413,972	07-02-2002	Takeda Chemical Industries, Ltd.	
		us- 2002/0103210	08-01-2002	Takeda Chemical Industries, Ltd.	
		^{US-} 5,807,869	09-15-1998	Takeda Chemical Industries, Ltd.	
		^{US-} 6,087,503	07-11-2000	Takeda Chemical Industries, Ltd.	
		^{US-} 6,346,534	02-12-2002	Neurocrine Biosciences, Inc.	
		^{US-} 6,537,998	03-25-2003	Neurocrine Biosciences, Inc.	,

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages			
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T ⁶		
_		WO 99/55358	11-04-1999	Praecis Pharmaceuticals Inc.				
		JP 2002-030087 (Abstract Only)	01-29-2002	Takeda Chemical Industries		V		
		JP 09-169766 (Abstract Only)	06-30-1997	Takeda Chemical Industries		7		
			1					

			
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Art Unit	1615		
Examiner Name	tba		
Attorney Docket Number	3040 FIGUD		

	U. S. PATENT DOCUMENTS				
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		US- 2002/0132820	09-19-2002	Neurocrine Biosciences, Inc.	
		^{US-} 6,162,813	12-19-2000	Merck & Co., Inc.	
-		^{US-} 6,150,522	11-21-2000	Merck & Co., Inc.	
		^{US-} 6,147,088	11-14-2000	Merck & Co., Inc.	
		^{US-} 6,150,352	11-21-2000	Merck & Co., Inc.	
		US-			7
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ^{3 "} Number ^{4 "} Kind Code ⁵ (if known)	MM-DD-YYYY	7 ppiloant of Ottoa Doddinont	Or Relevant Figures Appear	7
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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²	
		T. HOSONO, et al., "Effect of Gonadotropin Releasing Hormone on Thermoregulatory Vasomotor Activity in Ovariectomized Female Rats", Brain Research, (1997), Vol. 754, pages 88 - 94		
		E. IATSIMIRSKAIA, et al., "Effect of Testosterone Suppression on the Pharmacokinetics of a Potent GnRH Receptor Antagoníst", Pharmaceutical Research, (2002), Vol. 19, No. 2, pages 202 - 208		
		D. LUTHIN, et al., "Characterization of Mono- and Diaminopyrimidine Derivatives as Novel, Nonpeptide Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists", Bioorganic & Medicinal Chemistry Letters 12, (2002), pages 3636 - 3639		
		D. LUTHIN, et al., "The Discovery of Novel Small Molecule Non-peptide Gonadotropin Releasing Hormone (GnRH) Receptor Antagonists", Bioorganic & Medicinal Chemistry Letters 12, (2002) pages 3467 - 3470		

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